FACTUAL ALLEGATIONS

25. There are hundreds of thousands of men in the United States who have prostate cancer. The hormone testosterone, naturally produced by men, promotes the growth and spread of prostate cancer. One method of treatment of prostate cancer has been the suppression or elimination of testosterone in men suffering from that disease. Testosterone in a man suffering from prostate cancer can be eliminated through the surgical removal of the testicles by a procedure called an orchiectomy. Alternatively, man's production of testosterone can be suppressed through the administration of either Lupron® or Zoladex (a direct competitor of Lupron®).

26. In the 1980s, Defendants began marketing Lupron® as a treatment for prostate cancer. In marketing Lupron®, Defendants employed and maintained extensive marketing and sales departments. Since at least the early 1990s, Defendants primarily sold and provided Lupron® to medical providers across the country.

27. Lupron® is administered to patients in liquid form by intramuscular injection, typically in the buttocks or arm, by a physician or a nurse under the supervision of a physician. At various times in the 1990s, and continuing to the present, Lupron® was available in daily, one month, three month and four month doses. It was typical that a patient whose prostate cancer was being treated with Lupron® would receive regular injections of Lupron® for the remainder of his life.

THE MEDICARE INSURANCE PROGRAM

28. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

29. The U.S. Department of Health and Human Services ("HHS") is an agency of the United States and is responsible for the funding, administration and supervision of the Medicare Program. The Health Care Financing Administration ("HCFA") is a division of HHS and is directly responsible for the administration of the Medicare Program. HCFA, in discharging those responsibilities, contracted with private insurance companies, known as intermediaries and carriers, to receive, review, and pay appropriate claims for reimbursement for the provision of care to Medicare beneficiaries.

30. The Medicare Program as a general matter does not cover the cost of prescription pharmaceuticals which a Medicare beneficiary obtains pursuant to a prescription and thereafter self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered by a medical provider. Since Lupron® is an injectable drug, it is covered under Medicare Part B.

31. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug based upon the payment methodology set forth in 42 C.F.R. §405.517, which regulation was published in the Federal Register on November 25, 1991 and became effective on or about January 1, 1992.

32. Prior to January 1, 1998, the Medicare Part B allowed amount for injections of Lupron® was on the basis of the lower of the "estimated acquisition cost" or 95% of the "national average wholesale price", the AWP, for the drug. The estimated acquisition cost for a drug could be determined by the Medicare program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP

published in the Red Book that has been used to develop Medicare reimbursement. On January 1, 1998, this regulation was changed to provide that the allowed amount would be based upon the lower of the actual charge on the Medicare claim for benefits or 95 percent of the AWB for the drug.

33. Medicare Part B reimburses medical providers 80% of the allowable amount. The remaining 20% is paid by the Medicare beneficiary, and is called the "co-payment" amount. All medical providers are required by law to not only send the patient a bill for the 20% co-payment, but they are also required to make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable. Accordingly, all members of the Class may have paid some or all of the inflated co-payment amount.

34. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, in FM AB-99-63 (as of January 1, 1998) it states that drug and biologicals are paid based on the lower of the actual billed charge of 95 percent of the AWP reflected in pharmaceutical industry publication sources such as the Red Book, Blue Book, or Medispan.

35. The Red Book and other publications published AWP's for the various dose forms of Lupron®, as well as Zoladex and many other drugs. In periodically announcing the AWP for Lupron®, the Red Book and other publications simply published the prices that were supplied to them by Defendants. Defendants knew that they could and did directly control and raise the AWP for Lupron® at any time by simply forwarding to the Red Book, or any other publication, a new and higher AWP.

36. On May 23, 1999 The Chicago Tribune reported that a spokesman for the publisher of the Red Book, Medical Economics Co., stated that the AWP for Lupron® that appears in the Red Book is supplied by TAP. In fact, in a June 1996 Dow Jones News Article, it was reported that Phil Southerd, an associate product manager of the Red Book, stated that the Red Book merely publishes prices that are faxed right from the manufacturer.

37. There are significant discrepancies between the AWP set by Defendants for Lupron® Medicare reimbursement in the Red Book and the prices charged for Lupron® by Defendants to private sector purchasers. The AWP for Lupron® for Medicare set by Defendants does not reflect the plain meaning, or any reasonable interpretation of the terms "average" or "wholesale."

38. Therefore, Defendants' pattern of fraudulent conduct of artificially inflating the AWP for Lupron® above the actual average wholesale price directly caused Plaintiff and the Class, who paid all or part of the 20% co-payment for Lupron®, to substantially overpay.

DEFENDANTS' FRAUDULENT CONDUCT

Artificially Inflating the Average Wholesale Price

39. During the Class Period, Defendants deliberately and intentionally charged medical providers across the United States, a price substantially less than the AWP that Defendants had reported to Red Book for Medicare reimbursement. Defendants perpetuated this scheme so that the medical providers who purchased Lupron® at a low cost, could bill Medicare at the inflated AWP and earn a substantial profit from the "spread" between the retail cost and medicare reimbursement rate. This profit potential was created and marketed by Defendants to influence a medical provider's decision to recommend Lupron® and thereby increase Defendants' market share and revenues.

40. Defendants knew and understood that the Medicare Program relied upon the Red Book to establish the AWP, and because Defendants controlled the AWP as published in the Red Book, Defendants could manipulate the medical providers' profit. By artificially inflating the amount of profit obtained by physicians from Medicare and members of the Class, Defendants directly increased the demand for Lupron® and, accordingly, Defendants could inflate the amount of market share and profit they received from Lupron®.

41. As part of Defendants' scheme to increase their market share and revenues, they also induced increased Lupron® sales by telling medical providers to charge Medicare the AWP then published in the Red Book. According to Criminal Informations filed against several doctors, Defendants referred to this inflated profit and the corresponding inducement to the physicians as its "Return to Practice" program, among other names. Defendants referred to the profit that the doctor could obtain by prescribing Lupron® and billing the Medicare program at the published AWP as money going to the doctor from "[Defendants'] Checkbook." Defendants knew and understood that, because the Medicare Program relied upon the Red Book to establish AWP's, and because Defendants could precisely control the AWP as published in the Red Book, Defendants could increase the AWP whenever they so desired the profit obtained by physicians from the Medicare Program and the Class. Accordingly, Defendants could control the amount of the financial incentive, or "Return to Practice" that a physician would receive by prescribing Lupron® to their patients and billing Medicare at the AWP established by Defendants. *See, e.g.*, Information of *United States of America v. Spinella* (D. Mass. Dec. 8, 2000).

42. For example, the Criminal Information against Dr. Spinella states that, on or about August 24, 1995, in an attempt to get Dr. Spinella to reverse his decision of prescribing Zoladex,

rather than Lupron®, an employee of Defendants left at his office a document created by Defendants demonstrating to the doctor the amount of profit that he could earn, through Defendants' "Return to Practice" program, from the use of Lupron®. Specifically, the document showed that Dr. Spinella could earn as much as $7,000 per year more by using Lupron® instead of Zoladex. *See* Information of *United States of America v. Spinella* (D.Mass. Dec. 8, 2000).

43. The increase of $7,000 per year was based on the "spread" between Dr. Spinella's actual costs and the artificially inflated AWP set by Defendants used by Medicare for reimbursement.

44. The AWP reported in the Red Book for an injection of a monthly does of Lupron® 7.5 mg administered to a patient was as follows:

	Average Wholesale Price
1992	$418.75-$437.50
1993	$451.25
1994	$463.75
1995	$477.50
1996	$496.25-$515.63
1997	$540.63
1998	$566.88

45. Defendants' marketing and sales documents, which were prepared and disseminated to their employees and agents, compared the cost of Lupron® to its competitor Zoladex. For example, in 1996, Defendants prepared marketing materials for medical providers showing how they could make money by purchasing Lupron® from Defendants. As Defendants' marketing and sales materials indicated, in 1996, the AWP for Lupron® as reported for Medicare reimbursement was $515.63. However, in 1996 the actual price paid by the medical provider to Defendants for Lupron® ranged from a high of only $412.50 to a low of $350.81 if volume

discounts were achieved. *See* Information of *United States of America v. Spinella* (D.Mass. Dec.8, 2000).

46. Other documents created and disseminated by Defendants compared the AWP and the actual "cost" for Lupron® and Zoladex so that medical providers could easily see the different "Return-to-Practice" amounts are available for different levels of purchases.

47. Defendants used the artificially inflated AWP as a means of marketing its cancer drug Lupron®. Specifically, when employees of Defendants talked to providers about their choice of using Lupron® rather than Defendants' competitor's cancer medication Zoladex, Defendants emphasized that because its AWP was high the monetary return to the providers was better if they used Lupron®. Internal documents from Defendants specifically show that they used the spread to create greater demand for Lupron®. One such internal document stated:

> As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would stop if the allowable issue was taken care of.

48. The benefit of Defendants' illegal marketing and sales scheme is shown in increased market share and sales of Lupron®. In 2000, Lupron® sales were nearly $800 million as compared to $584 million in 1998. Most of the revenue obtained from Lupron® was from reimbursement from Medicare and the Class.

Use of Free Samples

49. Defendants, through their employees and agents, also provided free samples of Lupron® to medical providers. The free samples would be used to off-set the total cost associated with Lupron® purchases thereby increasing the spread. Moreover, Defendants

specifically told medical providers that they could and should still bill Medicare for the free samples.

50. One of Defendants' sales representatives called on Dr. Joseph Spinella in 1995 and reported to a District Manager employed by Defendants in Massachusetts. That District Manager supervised a number of Defendants' sales representatives who called upon urologists in Connecticut, Massachusetts, Maine and Rhode Island. From time to time, beginning in or about 1995, that Massachusetts District Manager informed Defendants' sales representatives that free doses of Lupron® could be offered to physicians to induce them to prescribe Lupron® to their patients and to keep them from switching patients to Zoladex. Defendants' sales representatives, supervised by that same District Manager, sent to the District Manager so-called Weekly Activity Reports and sales call notes, or portions thereof, which contained requests by physicians for samples, and the offer and delivery of samples to physicians to keep and to maintain their Lupron® business. *See* Information of *United States of America v. Spinella* (D.Mass. Dec. 8, 2000).

51. The health care providers were a necessary component of Defendants' scheme. For example, in April 2001, Dr. Joel Olstein, a Lewiston, Maine urologist, was charged with conspiring with TAP to bill insurance companies for free samples of Lupron®. In a telephone interview with Dr. Olstein, conducted by Chicago Tribune reporter Bruce Japsen on April 11, 2001, Dr. Olstein said that he planned to plead guilty in exchange for his cooperation in the investigation. "My plea is a conspiracy with TAP.... Did they tell me what to do? On some level there was some understanding.... For every new patient I started on Lupron®, they provided me a free dose of the drug," he added. "They wanted me to carefully track how many

new patients I started on Lupron® and we kept lists. Anybody in practice knows how to bill for free samples."

52. The Criminal Information against Dr. Olstein specifically alleges "The core objective of this conspiracy for all participants was to obtain money from the patient's health care insurers through the prescription of Lupron®. It was the objective of [TAP] in this conspiracy to provide free doses or samples of Lupron Depot®, as well as other things of value, including money, to physicians as an inducement to those physicians to order Lupron Depot®."

Other Financial Inducements

53. Defendants have also provided and/or arranged for many other financial inducements to stimulate sales of Lupron® at the expense of Plaintiff and the Class. Such inducements included, but were not limited to, several kickbacks which consisted of free drugs, trips to resorts, and free consulting services to doctors and other customers, among other things.

54. Defendants conspired and agreed to accomplish the fraudulent scheme set forth herein in order to increase the sale of Lupron®, and committed acts in furtherance of this conspiracy which are outlined in this Complaint.

55. In furtherance of this scheme to defraud Medicare and the Plaintiff Class, Defendants have created a centralized national marketing and sales plan which was implemented through their employees and agents in the following manner, among others:

(a) Setting an actual average wholesale price at which it sold Lupron®;

(b) Setting the AWP in the Red Book and other similar publications which was materially greater than the actual average wholesale price;

(c) Contacting the Red Book and other industry publications for the

purpose of setting and controlling the listed AWP;

(d) Sending informing to medical providers about both the Red Book quoted AWP and the actual average wholesale price for Lupron®;

(e) Creating and disseminating marketing and sales materials that showed the spread between the actual average wholesale price and the AWP reported in the Red Book for Medicare reimbursement;

(f) Creating and disseminating marketing and sales materials for medical providers discussing how the use of free samples can increase their profits;

(g) Creating and disseminating marketing and sales materials for medical providers discussing other financial inducements available from Defendants for the usage of Lupron®;

(h) Inducing Medicare patients and their supplemental insurers to pay the inflated co-payment for Lupron® in reliance on the inflated AWP;

(i) Engaging in telephone conversations and mailings, to and from medical providers, to effectuate their fraudulent marketing scheme;

(j) Receiving the proceeds of Defendants' scheme;

(k) Distributing the proceeds of Defendants' scheme to medical providers in the form of free samples, lower actual average wholesale price's for Lupron® and other financial inducement; and

(l) Mailing promotional literature to medical providers outlining how they could increase profits by using Lupron®.

56. Defendants concealed their fraudulent conduct from the Plaintiff and the Class by controlling the process by which the AWP was set. Defendants prevented Class Members from knowing what the actual costs for Lupron® were, as well as by failing to inform them of the usage of free samples and the providing of other financial incentives to medical providers to induce them to use Lupron®. Moreover, Defendants fraudulent conduct was of such a nature as to be self-concealing.

57. Defendants created and managed an enterprise of great geographic scope and financial impact through which they defrauded Plaintiff and the Class out of millions of dollars, through a pattern of racketeering activity that included the mailing or interstate wire transmission of thousands of marketing and sales materials relating to Lupron® and Medicare reimbursement rates. Defendants also used the mail and wires to set the AWP with the Red Book and other similar publications as well as for arranging the other financial inducements discussed herein.

58. Plaintiff was diligent in pursuing an investigation of the claims asserted in this complaint. Through no fault of his own, he did not receive inquiry notice nor learn of the factual basis for his claims in this complaint and his injuries suffered therefrom until recently.

TOLLING OF THE STATUTE OF LIMITATIONS

59. Plaintiff had no knowledge of the conspiracy, concerted action and other unlawful conduct alleged herein, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence, until approximately October 3, 2001 when it was announced that Defendants agreed to plead guilty to a conspiracy to violate the PDMA. Plaintiff could not have discovered the conspiracy, concerted action or other unlawful conduct alleged herein at an earlier date by the exercise of due diligence because of the deceptive practices and techniques of

secrecy employed by Defendants and their co-conspirators to avoid detection of and conceal their unlawful conduct and conspiracy. These techniques of secrecy included, but were not limited to, secret meetings and communications, misstatements about the AWP, and other conduct alleged herein.

60. Because the unlawful conduct and conspiracy was kept secret by Defendants and their co-conspirators, Plaintiff was unaware of the fact that the prices of Lupron® were secretly agreed upon and artificially set as alleged herein.

61. By reason of the foregoing, the claims of Plaintiff and members of the Class are timely under any applicable statute of limitations (as tolled by the filing of this class action Complaint) pursuant to the discovery rule and the doctrine of fraudulent concealment.

62. The Defendants have been aware of their unlawful conduct and conspiracy since at least 1991, and probably from before then.

63. Despite this knowledge and awareness, the Defendants have continued to promote and sell Lupron® at artificially inflated prices.

64. The Defendants' failure to properly disclose their unlawful conduct and conspiracy, and other acts and omissions as alleged herein, was and is willful, wanton, malicious, outrageous, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of the plaintiff and members of the Plaintiff's Class.

COUNT I

UNJUST ENRICHMENT

65. Plaintiff hereby incorporates by reference thereto the averments of paragraphs 1 through 64 hereof as if fully set forth here and further allege as follows.

66. By engaging in the conduct described in this Complaint, Defendants have knowingly obtained benefits from Plaintiff and the Class under circumstances such that it would be inequitable and unjust for these Defendants to retain them.

67. Defendants have collected payments for Lupron® from Plaintiff and the members of the Class that vastly exceeded the payments to which Defendants were entitled as a matter of law.

68. Defendants will be unjustly enriched if they are permitted to retain the full amounts paid to them by Plaintiff and the members of the Class.

69. Plaintiff and the members of the Class are therefore entitled to an award of compensatory and punitive damages in an amount to be determined at trial or the imposition of a constructive trust upon the profits derived by Defendants by means of the overcharges they imposed upon Plaintiff and the members of the Class.

70. Plaintiff and the members of the Class have no remedy at law to prevent Defendants from continuing the inequitable conduct alleged herein.

WHEREFORE, Plaintiff, on behalf of himself and the members of the Class, respectfully seeks the relief set forth below.

COUNT II

FRAUD

71. Plaintiff and the Class hereby incorporate by reference thereto the averments of paragraphs 1 through 70 hereof as if fully set forth here and further allege as follows.

72. By engaging in the acts and omissions alleged in this Complaint, Defendants have committed fraud on the Plaintiff and the Class.

73. These Defendants intended that Plaintiff and the Class would rely on their statements and representations with respect to the inflated AWP, among other things, to the detriment of Plaintiff and the Class. Plaintiff and the Class did in fact reasonably rely on the false representations and statements of these Defendants and suffered injury and damages thereby, as more fully set forth herein.

74. In addition, these Defendants concealed and suppressed material facts about their unlawful agreements and discussions with one another and others, and they concealed and suppressed their unlawful acts and omissions as set forth more fully herein. Among other things, these Defendants concealed and suppressed the fact that the AWP upon which the price paid for Lupron® by Plaintiff and the Class was based was artificially inflated, thereby causing Plaintiff and the Class to pay more for Lupron® than they otherwise would have.

75. Plaintiff and the Class were unaware of the above-referenced facts, and would not have paid the artificially inflated price for Lupron® that they did had they known of the facts Defendants concealed and suppressed.

76. As a direct and proximate result of Defendants' fraudulent conduct, and the concealment and suppression of material facts by Defendants, Plaintiff and the Class have suffered and will continue to suffer damages.

WHEREFORE, Plaintiff, on behalf of himself and the members of the Class, respectfully seeks the relief set forth below.

COUNT III

CIVIL CONSPIRACY/CONCERT OF ACTION

77. Plaintiff and the Class hereby incorporate by reference thereto the averments of

paragraphs 1 through 76 hereof as if fully set forth here and further allege as follows.

78. Beginning at least as early as 1991, the exact date being unknown to Plaintiff and the Class, and continuing thereafter until at least 1998, Defendants and their co-conspirators engaged in a continuing conspiracy and/or concerted action to violate the PDMA and to defraud the Plaintiff and the Class by causing Plaintiff and the Class to pay more for Lupron® than they otherwise would have in the absence of Defendants' conspiracy and/or concerted action.

79. According to the United States Department of Justice, on or before October 3, 2001, Defendants, by and through their joint venture, TAP, agreed to plead guilty to a conspiracy to violate the PDMA and to pay a $290 million criminal fine, the largest criminal fine ever in a U.S. health-care fraud prosecution case. Additionally, defendant agreed to settle the government's claims for $875 million, which consisted of the $290 million criminal fine, $559.5 million in civil liabilities for filing false and fraudulent claims, and $25.5 million in civil liabilities to fifty states and the District of Columbia.

80. Pursuant to their conspiracy and/or concerted action alleged herein, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud the Plaintiff and the Class. Those activities include the following:

(a) Defendants discussed and agreed among themselves and with their co-conspirators that they would fix the AWP for Lupron®;

(b) Defendants discussed and agreed among themselves and with their co-conspirators that they would provide free samples to medical providers; and

(c) Defendants and their co-conspirators discussed and agreed among themselves and with their co-conspirators that they would, including but not limited to, perform and/or allow those acts and conduct set forth within paragraph 55 as well as otherwise set forth within this Complaint.

81. As a result of Defendants' conspiracy and concerted action as alleged herein, Plaintiff and the Class have been injured and damaged.

WHEREFORE, Plaintiff, on behalf of himself and the members of the Class, respectfully seeks the relief set forth below.

COUNT IV

VIOLATION OF CONSUMER PROTECTION STATUTES

82. Plaintiff and the Class hereby incorporate by reference thereto the averments of paragraphs 1 through 81 hereof as if fully set forth here and further allege as follows.

83. Plaintiff and Class are consumers who Lupron® for personal use. All fifty states and the District of Columbia have enacted statutes to protect consumers against unfair, deceptive or fraudulent business practices, unfair competition and false advertising. Most states allow consumers a private right of action under these statutes.

84. By the misrepresentations and non-disclosure of material facts alleged above, the Defendants deceived and continues to deceive consumers, such as Plaintiff and the Class. This conduct constitutes unlawful, unfair, unconscionable, deceptive and fraudulent business practices within the meaning of state consumer protection statutes and in New Jersey specifically N.J.S.A. 56:8-1, *et seq.*

85. In addition, the Defendants' use of media to promote the sale of Lupron® through

false and deceptive representations as alleged above constitutes unfair competition and unfair, deceptive, untrue, or misleading advertising within the meaning of state consumer protection statutes.

86. As part of their guilty plea and payment of fines and money for civil liabilities, Defendants agreed to pay the sum of $25.5 million in civil liabilities to fifty states and the District of Columbia. Such admission of liability and payment of civil liabilities to the states and the District of Columbia bodes in favor of the application of the laws of such states and the District of Columbia to Defendants in this Court.

87. As a result of the Defendants' unfair and deceptive trade practices throughout the fifty states and the District of Columbia, Plaintiff and the Class have or will suffer damages in an amount to be determined at trial.

WHEREFORE, Plaintiff, on behalf of himself and the members of the Class, respectfully seeks the relief set forth below.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the Class request the Court to enter the following relief:

(a) Certify this case as a class action pursuant to New Jersey Court Rules 4:32-1, *et seq.*;

(b) Enter judgment against all Defendants for the violations alleged herein;

(c) Enjoin the Defendants from committing the acts complained of herein,

(d) Award the actual damages incurred by Plaintiff and the members of the Class as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by

law;

(e) Order that Defendants disgorge all profits unjustly gained as a result of their conduct alleged herein;

(f) Award punitive damages and specifically in New Jersey treble damages pursuant to N.J.S.A. 56:8-1 *et seq.*, as well as whatever additional punitive damages are allowed in statutes of other states.

(g) Award Plaintiff the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and

(h) Award such other and further relief as the Court may deem just under the circumstances.

JURY DEMAND

Plaintiff and the Class demand a trial by jury of all issues so triable in this cause.

COOPER PERSKIE APRIL NIEDELMAN
WAGENHEIM & LEVENSON
A Professional Association

By: _____
LEWIS B. APRIL

Dated: October 8, 2001

Jonathan Cohen, Esquire
Kline & Specter

Patrick Cafferty, Esquire
Bryan Clobes, Esquire
Miller, Faucher

Bernard Persky, Esquire
Goodkind Labaton

Attorneys for Plaintiff, Bernard Walker and the Class

CERTIFICATION PURSUANT TO RULE 4:5-1

The undersigned, Lewis B. April, certifies on behalf of the above named Plaintiff as follows:

1. I am an attorney admitted to practice law in the State of New Jersey, with the firm of Cooper Perskie April Niedelman Wagenheim & Levenson, counsel for the above named Plaintiff.

2. The matter in controversy in this matter is not the subject of any other action pending in any Court or of a pending arbitration proceeding, nor is any other action or arbitration proceeding contemplated.

3. At this time, there are no other parties who should be joined in this action.

4. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

LEWIS B. APRIL

Dated: October 8, 2001

EXHIBIT 10

STATE OF NORTH CAROLINA NEW HANOVER COUNTY	IN THE GENERAL COURT OF JUSTICE SUPERIOR COURT DIVISION
HARRY E. STETSER, DALE E. NELSON, and MICHAEL de MONTBRUN, individually and on behalf of themselves and all others similarly situated, Plaintiffs, v. TAP PHARMACEUTICAL PRODUCTS INC.; ABBOTT LABORATORIES; TAKEDA CHEMICAL INDUSTRIES, LTD.; JOHNSON & JOHNSON; ETHICON ENDO-SURGERY, INC.; INDIGO LASER CORPORATION; DAVID JETT; CHRISTOPHER COLEMAN; SCOTT HIDALGO; and EDDY JAMES HACK, Defendants.	1CV 5268 S FILE NO. _____ COMPLAINT CLASS ACTION (Jury Trial Demanded)

COMPLAINT

Plaintiffs, by their attorneys, bring this Complaint on their own behalf and on behalf of all others similarly situated to obtain declaratory relief, damages, costs of suit, attorneys' fees and other appropriate relief from the Defendants. Plaintiffs complain and allege, upon information and belief, as follows:

NATURE OF ACTION

1. This case is brought by Plaintiffs, Harry E. Stetser, Dale E. Nelson and Michael de Montbrun, as a class action on behalf of potentially thousands of individuals and entities to recover monies overpaid as a result of Defendants' fraudulent scheme that targeted three types of patients:

(1) "Government Assistance Patients": those who subscribe to and rely on one or more government assistance programs for the partial payment of their medical care and treatment; including, Medicare, Medicaid, and TRICARE (formerly CHAMPUS) (hereinafter referred to collectively as "government assistance programs"); (2) "Private Assistance Patients": those who subscribe to and rely on private health insurance carriers for the partial payment of their medical care and treatment, and (3) "No Assistance Patients": those who have no insurance at all for the payment of their medical care and treatment.

2. Defendants are Abbott Laboratories ("Abbott"), Takeda Chemical Industries, Ltd. ("Takeda"), TAP Pharmaceutical Products Inc. ("TAP") (a wholly owned joint venture of Abbott and Takeda, and prior to April 2000 known as TAP Holdings, Inc.), Johnson & Johnson ("J&J"), Ethicon Endo-Surgery, Inc. ("Ethicon")(a wholly owned subsidiary of J&J), Indigo Laser Corporation ("Indigo")(a wholly owned subsidiary of J&J and Ethicon), David Jett ("Jett")(an employee of Indigo), Christopher Coleman ("Coleman")(an employee of Indigo), Scott Hidalgo ("Hidalgo")(an employee of Indigo), and Eddy James Hack ("Hack")(owner and operator of Oncology Solutions a\k\a International Oncology Network) [collectively referred to herein as "Defendants"].

3. Defendants Abbott, Takeda and TAP are manufacturers and sellers of drug known as Lupron® who have pleaded guilty to federal criminal and civil fraud charges for, among other things, conspiring to violate the Prescription Drug Marketing Act ("PDMA") by, *inter alia*, artificially setting and fixing the prices of Lupron® sold in the United States, including North Carolina. This conspiracy was in violation of the federal conspiracy statute, 18 U.S.C. § 371

(Conspiracy to Commit Offense or to Defraud United States). *See* Letter Agreement dated September 28, 2001, attached hereto as Exhibit "A."

4. Defendants J&J, Ethicon, and Indigo are manufacturers and sellers of, among other things, the Indigo LASEROPTIC Treatment System, a minimally invasive procedure that treats patients with enlarged prostates, otherwise known as benign prostatic hyperplasia ("BPH"). BPH is a condition that often attends or coincides with prostate cancer.

5. Defendants Jett, Coleman and Hidalgo, at all times material hereto, were employees and sales representatives of Indigo, a wholly-owned subsidiary company of Defendants J&J and Ethicon. Defendant Hack, at all times material hereto, was the owner and operator of Oncology Solutions a\k\a International Oncology Network, the nations largest community-based oncologist network. These Defendants all pled guilty to a one-count Criminal Information charging the same conspiracy in connection with a violation of the PDMA (unlicensed wholesaling of prescription drugs). In particular, these Defendants pled guilty to, *inter alia*, assisting in a conspiracy (presumably with other Defendants herein) involving the unlawful diversion of Lupron® by physicians to circumvent federally controlled pricing markets for profit. These Defendants also pled guilty to receiving kickbacks for their efforts in furtherance of the conspiracy.

6. Because of Defendants' unlawful conduct, Plaintiffs and Class members paid artificially inflated prices for Lupron®.

7. During the period from at least 1991 through at least October, 2001, the exact dates of which are unknown by Plaintiffs at this time, Defendants created and implemented a fraudulent marketing, pricing and sales scheme to defraud Lupron® patients by substantially increasing the sales of Lupron® and reaping unlawful profits at the expense of patients who took Lupron®. Among other

things, Defendants systematically, among themselves and with other entities and individuals, created a pervasive illegal system to cause patients on Lupron® to overpay substantial amounts of money for the specific purpose of increasing the market share of Lupron® and maximizing their profits at the expense of Plaintiffs and the Class. The improper marketing, pricing and sales practices relate to, *inter alia*, the following: (a) deliberately overstating the average wholesale price ("AWP") for Lupron®, the rate upon which reimbursements under government assistance and certain private insurance programs are set, including the co-payment portions paid by Government Assistance Patients and Private Assistance Patients, so that both the government (through Medicare, Medicaid, TRICARE and other programs), private insurers (through private insurance programs) and Government and Private Assistance Patients, including Plaintiffs, paid artificially inflated amounts of money for Lupron®; (b) providing free samples of Lupron® to medical providers and instructing them that they could and should bill government and private assistance programs, and Government, Private and No Assistance Patients on Lupron®, for such free samples; and (c) providing other unlawful financial inducements to medical providers to prescribe Lupron®, causing Plaintiffs and members of the Class to pay artificially inflated prices for Lupron®.

8. On or before October 3, 2001, Defendants Abbott, Takeda and TAP agreed to plead guilty to having fraudulently priced and marketed Lupron®. In particular, Defendants Abbott and Takeda, by and through their joint venture, TAP, agreed to plead guilty to a conspiracy to violate the PDMA and agreed to pay a $290 million criminal fine, the largest criminal fine ever in a U.S. health-care fraud prosecution case, according to the United States Department of Justice. Additionally, Defendants agreed to settle criminal and civil claims brought by the federal government for $875 million, which amount consisted of the $290 million criminal fine, $559.5 million in civil liabilities

for filing false and fraudulent claims, and $25.5 million in civil liabilities to fifty states and the District of Columbia. (Because of an interest provision in the Civil Settlement Agreement, which required TAP to pay interest on the civil settlement commencing on September 4, 2001, the total amount that TAP will pay will be in excess of $884 million).

9. Defendants' conspiracy consisted of, *inter alia*, engaging in the practice of deliberately inflating the AWP, which is used by government assistance programs, like Medicare, for reimbursement. By deliberately inflating the AWP above the actual acquisition cost to the medical provider, these Defendants created a "spread" consisting of the difference between what these Defendants set as the AWP and the actual average wholesale price for non-Medicare usage. Such spreads were used by Defendants to create a profit-based incentive for medical providers to prescribe Lupron®.

10. The scheme allowed Defendants to control, as part of their sales and marketing strategies, how much reimbursement would be made under government assistance programs for Lupron®. Defendants deliberately marketed and promoted the sale of Lupron® based on the availability of inflated payments made by government assistance programs and their beneficiaries. The inflated payments – the amount by which what Defendants set as the AWP exceeded the actual cost of Lupron® to the medical provider – were often referred to by Defendants in internal documents as a "spread," "Return-To-Practice," "return-on-investment," and "profit." Defendants even prepared side-by-side comparisons of the spreads available on Lupron® versus their competitor's drugs. These comparisons were used as a marketing and sales pitch to medical providers. As a result, senior citizens, men with cancer, women and children alike who took Lupron® and paid some or all of the cost of the drug have paid millions of dollars in inflated drug prices.

11. Twenty percent (20%) or more of these inflated government assistance payments come directly out of the pockets of Plaintiffs and Government Assistance Patient Class Members through co-payments and deductibles.

12. Others who took Lupron®, Private Assistance Patients, who may not have been covered by any government assistance programs, but were covered by certain private assistance programs, likewise paid a percentage portion of the artificially inflated cost of the drug.

13. Finally, those who took Lupron®, but were not covered be either government or private assistance programs, paid substantially more than 20% of the artificially inflated cost of the drug. Indeed, some of these No Assistance Patients paid the full inflated cost of Lupron®.

14. In addition to the above-named Defendants, several employees of TAP have been charged by the United States Department of Justice ("DOJ") with various crimes as part of the overall conspiracy alleged herein. Charged with conspiracy were:

a. Kimberlee Chase of Dedham, Massachusetts, formerly a District Manager employed by TAP;

b. Janice M. Swirski of Chestnut Hill, Massachusetts, formerly a National Account Manager employed by TAP;

c. Donna Tom of New York, New York, formerly a District Manager employed by TAP;

d. David Guido of Quaker Hill, Connecticut, currently a Hospital Account Executive employed by TAP;

e. Henry Van Mourick of Roseville, California, currently a District Manager employed by TAP; and

f. Alan MacKenzie of Barrington, Illinois, formerly Vice President of Sales for TAP.

Further charges were levied against certain of these individuals as follows: Ms. Chase was charged with 63 counts involving illegal kickbacks and aiding and abetting; Ms. Swirski was likewise charged with providing illegal kickbacks.

15. In addition, several urologists have pleaded guilty to federal Criminal Informations charging them with participating in the conspiracy with TAP and the other Defendants to defraud government assistance programs, and ultimately Plaintiffs and the Class, regarding the marketing and sale of Lupron®. At the time of this Complaint, the following medical providers have all pleaded guilty to participation in the conspiracy to, *inter alia*, defraud government assistance programs and their beneficiaries, including Plaintiffs and the Class:

a. Dr. John Romano of Plymouth, Massachusetts;

b. Dr. Elias J. Jacobs of Winter Park, Florida;

c. Dr. Steven K. Brooks of Longwood, Florida;

d. Urology Consultants, Inc. of Longwood, Florida;

e. Dr. Joseph S. Olstein of Lewiston, Maine;

f. Dr. Rodney Mannion of LaPorte and Michigan City, Indiana;

g. Dr. Jacob Zamstein of Bloomfield, Connecticut;

h. Dr. Joseph Spinella of Bristol, Connecticut.

16. According to the various Informations, Defendants provided medical providers, such as those listed above, with free samples and other financial incentives as inducements to increase the usage of Lupron®. *See, e.g., United States of America v. Spinella*, (D. Mass. Dec. 8. 2000); *United*

States of America v. Mannion, (D. Mass. Feb. 28, 2000); *United States of America v. Zamstein*, (D. Mass. Nov. 3, 2000); *United States of America v. Olstein*, (D. Mass. April 11, 2001) ("Criminal Informations").

17. Such financial inducements caused medical providers to prescribe Lupron® for their patients over competitor drugs, such as Zoladex, and over potentially alternative courses of treatment for their patient's prostate cancer.

18. Moreover, on April 20, 2001, Abbott filed a Form 10-K wherein it disclosed:

> Abbott Laboratories today announced an adjustment in litigation reserves to reflect recent developments related to the U.S. Department of Justice investigation into the marketing and sales practices of TAP Pharmaceutical Products Inc. for Lupron®. TAP Pharmaceutical Products Inc. is a 50/50 joint venture between Abbott and Takeda Chemical Industries, Ltd. Discussions between TAP and the Department of Justice are ongoing. The government's inquiry has focused solely on marketing and sales practices, and does not involve the safety and efficacy of Lupron®. This one-time adjustment in the litigation reserves will cause an adjustment to previously announced first quarter results, as reflected in the attached table. While it is not feasible to predict the outcome of this proceeding with certainty, no material impact on operations, or additional one time charges are expected.

19. The United States Government sought to recover only its portion of the fraudulent charges, which represents between 75-80% of the overpayments caused by Defendants to government assistance program recipients, depending on the program. For instance, CHAMPUS provided reimbursement of 75% of the cost of Lupron® while Medicare provided reimbursement of 80% of the cost.

20. Absent this litigation, neither Plaintiffs nor other Government Assistance Patients would recover from Defendants the remaining 20-25% overpayments they made through co-payment

and/or deductible amounts they paid for Lupron®. In addition, absent this litigation, Private Assistance Patient members of the Class, who also suffered as a result of being overcharged for Lupron® and/or were unlawfully charged for free samples of Lupron®, would not recover. Finally, absent this litigation, No Assistance Patient members of the Class, who may have paid the full price for Lupron®, would not recover.

21. The Plaintiffs have asserted claims under the common law and statutes of North Carolina and other states, as well as the District of Columbia.

JURISDICTION AND VENUE

22. Plaintiffs bring this action pursuant to state consumer protection and antitrust statutes, as well as the common law of all states. This Court has subject matter jurisdiction because this is an action for damages which, in the aggregate, exceeds $10,000 exclusive of interest, costs and attorneys' fees, although neither Plaintiff nor any individual member of the Class (as defined below) has suffered damages in excess of $74,999.

23. This Court has jurisdiction over Defendants Abbott, Takeda, TAP, J&J, Ethicon and Indigo because they are corporations regulated under the laws of the State of North Carolina and do sufficient business in, have sufficient minimum contacts with, or otherwise intentionally avail themselves of the markets of the State of North Carolina through the promotion, marketing, sale and use of Lupron® and other drugs and products in North Carolina.

24. This Court has jurisdiction over Defendants Jett, Coleman, Hidalgo, and Hack because they are individuals who either reside or work in North Carolina, have sufficient minimum contacts with or otherwise purposefully avail themselves of the markets of the State of North Carolina, and/or are employed by corporations regulated under the laws of the State of North

Carolina and which do sufficient business in, have sufficient minimum contacts with, or otherwise intentionally avail themselves of the markets of the State of North Carolina through the promotion, marketing, sale and use of Lupron® and other drugs and medical products in North Carolina, as set forth more fully below.

25. Venue is proper in this Court since Plaintiffs, as well as numerous Class members, purchased Lupron® from doctors and hospitals located in this County and North Carolina, and otherwise engaged in the transactions which form the basis of this action by having paid for Lupron®. Plaintiffs Harry Stetser and Dale Nelson are residents of Pitt County.

PARTIES

26. Plaintiff, Harry E. Stetser, is an individual and resident of the State of North Carolina who resides in Winterville, Pitt County, North Carolina. Mr. Stetser was recently diagnosed with prostate cancer and has been prescribed and has taken Lupron® for the treatment of his condition. He has made several purchases of Lupron® in North Carolina for his treatment and was charged the AWP for Lupron® each time. Mr. Stetser has Medicare Part B which pays for 80% of his Lupron® prescription purchases. The remaining 20% co-payment has been paid in part directly by Mr. Stetser and in part by his private insurer. Accordingly, Mr. Stetser suffered direct injury and damages as a result of Defendants' unlawful conduct set forth herein.

27. Plaintiff, Dale E. Nelson, is an individual and resident of the State of North Carolina who resides in Greeneville, Pitt County, North Carolina. Mr. Nelson is a veteran and is a retired Master Sergeant (E-7) in the United States Air Force. He was diagnosed with prostate cancer in 1992 and was prescribed and took Lupron® for the treatment of his condition from approximately June 1992 until approximately August 1992. He made purchases of Lupron® in North